



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 150

[Docket No. FDA-1997-P-0007] (formerly Docket No. 1997P-0142)

Artificially Sweetened Fruit Jelly and Artificially Sweetened Fruit Preserves and Jams; Proposed Revocation of Standards of Identity

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA or we) is proposing to revoke the standards of identity for artificially sweetened jelly, preserves, and jams. We are taking this action primarily in response to a citizen petition submitted by the International Jelly and Preserve Association (IIPA). We are taking this action because we tentatively conclude that these standards are both obsolete and unnecessary in light of our regulations for foods named by use of a nutrient content claim and a standardized term. We also tentatively conclude that this action will promote honesty and fair dealing in the interest of consumers.

DATES: Submit electronic or written comments on the proposed rule by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. FDA-1997-P-0007 (formerly Docket No. 1997P-0142), by any of the following methods.

### Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

### Written Submissions

Submit written submissions in the following ways:

- FAX: 301-827-6870.
- Mail/Hand delivery/Courier (for paper or CD-ROM submissions): Division of Dockets Management, (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA-1997-P-0007 (formerly Docket No. 1997P-0142) for this rulemaking. All comments received may be posted without change to <http://www.regulations.gov>, including any personal information provided. For additional information on submitting comments, see the “Comments” heading of the SUPPLEMENTARY INFORMATION section of this document.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> and insert the docket numbers found in brackets in the heading of this document into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

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#### SUPPLEMENTARY INFORMATION:

##### I. Background

For more than 50 years, FDA has maintained standards of identity for fruit jelly (jelly) (21 CFR 150.140) and fruit preserves and jams (preserves and jams) (21 CFR 150.160). The standards establish the common or usual name for these products and provide that these products may contain nutritive sweeteners (e.g., sugar). In 1959, FDA added new standards of identity for artificially sweetened fruit jelly (artificially sweetened jelly) (21 CFR 150.141) and artificially sweetened fruit preserves and jams (artificially sweetened preserves and jams) (21 CFR 150.161) (24 FR 8896; October 31, 1959) that permit the use of non-nutritive sweeteners (e.g., saccharin). Notably, §§ 150.141 and 150.161 limit the types of non-nutritive sweeteners that can be used in products that are governed by those standards of identity. Such products may only use saccharin, sodium saccharin, calcium saccharin, or any combination thereof, and may not use newer forms of non-nutritive sweeteners that have been established since the standard of identity regulations were issued.

The Nutrition Labeling and Education Act (NLEA) of 1990 amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to provide for a number of fundamental changes in food labeling, leading to a new regulatory framework for the naming of foods that do not fully comply with the relevant standards of identity. In response to NLEA, FDA established in part 101 (21 CFR part 101), among other things, definitions for specific nutrient content claims using terms such as “free,” “low,” “light” or “lite,” and “less,” and provided for their use in food

labeling (58 FR 2302; January 6, 1993). FDA also prescribed at the same time in § 130.10 (21 CFR 130.10) a general definition and standard of identity for foods named by a nutrient content claim defined in part 101, such as “low calorie” or “sugar free,” in conjunction with a traditional standardized food term (58 FR 2431; January 6, 1993). A nutrient content claim applied to the standardized food “grape jelly,” for example, could be “low calorie grape jelly.” Section 130.10(d)(1) allows the addition of safe and suitable ingredients to a food named by use of a nutrient content claim and a standardized term when these ingredients are used to, among other things, add sweetness to ensure that the modified food is not inferior in performance characteristic to the standardized food even if such ingredients are not specifically provided for by the relevant food standard. Thus, under certain circumstances, § 130.10 permits manufacturers to use safe and suitable artificial sweeteners (e.g., aspartame) that are not expressly listed in §§ 150.141 and 150.161 in the manufacture of jelly, fruit preserves, and jams (collectively, “fruit spreads”). Therefore, fruit spread products named with a nutrient content claim (for example, “low calorie grape jelly”) may contain newer artificial sweeteners to add sweetness to fruit spread products so that they are not inferior in their sweetness compared to their standardized counterparts (for example, “grape jelly”). The provisions of § 130.10 do not require these products to declare the presence of such non-nutritive sweeteners within the name of these foods. FDA took this action to assist consumers in maintaining healthy dietary practices by providing for a modified version of a traditional standardized food to achieve a nutrition goal (e.g., reduction in sugar consumption or calories) and that has a descriptive name that is meaningful to consumers. The provisions of § 130.10 do not, however, permit the use of nutrient content claims as part of the name of a food for foods governed by standards of identity that established the phrase “artificially sweetened” as part of the standard of identity. Accordingly,

jelly, preserves, and jams, that use saccharin, sodium saccharin, calcium saccharin, or any combination thereof as non-nutritive sweeteners must still include the term “artificially sweetened” in their names and are not permitted to bear a nutrient content claim as part of the name; however, similar products that use newer non-nutritive sweeteners are governed by § 130.10 and must not include the term “artificially sweetened” in their names.

## II. IJPA Petition and Grounds

IJPA is a national trade association representing the manufacturers of jelly, preserves, jams, and nonstandardized fruit spreads, and suppliers of goods and services to the industry, including ingredient suppliers of fruit, sweeteners, and pectin. IJPA submitted a citizen petition dated March 31, 1997 (now Docket No. FDA-1997-P-0007), requesting the revocation of the standards of identity for artificially sweetened jelly, preserves, and jams. IJPA submitted its petition in response to FDA’s advance notice of proposed rulemaking announcing that FDA was planning to review its food standards regulations (60 FR 67492; December 29, 1995). In that document, we sought comments on, inter alia, the benefits or lack of benefits of such regulations in facilitating domestic and international commerce, the value of these regulations to consumers, and alternative means of accomplishing the statutory objective of food standards (i.e., to promote honesty and fair dealing in the interest of consumers in the manufacture and sale of food products covered by the standard of identity regulations).

IJPA asserts in its citizen petition that the standards of identity for artificially sweetened jelly, jams, and preserves are outdated. According to IJPA, the standards have not been updated to take into account new non-nutritive sweeteners that have been approved by FDA since 1959. The petition maintains that the general standard in § 130.10 provides fruit spread manufacturers with sufficient flexibility to use newer, intense non-nutritive sweeteners in lieu of traditional

nutritive sweeteners, and it would be appropriate to rely on that general standard rather than seek piecemeal amendments to the standards of identity to reflect the development of any new sweeteners. IJPA stated that by using the general standard in § 130.10, manufacturers can create products with nutrient content claims for reductions in calories or sugar content that are established in FDA regulations. According to IJPA, nutrient content terms (e.g., “low calorie”) also better communicate to the consumer the nutritional benefit of the use of non-nutritive sweeteners than does the term “artificially sweetened,” which is required to appear in the labels of products manufactured in conformity with §§ 150.141 and 150.161. Therefore, IJPA concluded in its petition that the standards of identity for artificially sweetened jelly, preserves, and jams are both obsolete and unnecessary, and requested that we revoke these standards. Finally, IJPA stated that as of the date of submission of its citizen petition, there were few products being manufactured under these two standards of identity and that some manufacturers are already using the general standard in § 130.10 to formulate products that have reduced sugar and caloric content. IJPA stated that if these standards are revoked, any products that are currently manufactured in conformity with the standards could remain on the market by operation of § 130.10.

### III. The Proposal

We have reviewed IJPA’s petition. We find merit in IJPA’s argument that revoking the artificially sweetened standards of identity would allow manufacturers to more accurately and consistently describe the attributes of the fruit spreads that currently conform to those standards. We therefore tentatively conclude that revoking the standards would promote honesty and fair dealing in the interest of consumers and is, thus, appropriate under section 401 of the FD&C Act (21 U.S.C. 341). We tentatively reach this conclusion because we find that nutrient content

claims, such as “low calorie” or “reduced sugar” better characterize the nutritional profile of the affected fruit spreads than does the term “artificially sweetened.” Further, revoking §§ 150.141 and 150.161 provides manufacturers with the flexibility to use the three non-nutritive sweeteners listed in those standards while also naming their products using FDA-defined nutrient content claims, in accordance with § 130.10. Moreover, other safe and suitable artificial sweeteners that might be developed in the future could be used in these products under § 130.10 without the need to further revise relevant standards of identity.

Enactment of NLEA and the development of newer artificial sweeteners, thus, renders the standards of identity for artificially sweetened jelly, preserves, and jams in §§ 150.141 and 150.161 obsolete. They no longer serve their intended purpose of ensuring honesty and fair dealing while allowing for the use of artificial sweeteners in standardized fruit jelly and standardized fruit preserves and jams as firms may now use certain artificial sweeteners under § 130.10. The standards for artificially sweetened jelly and artificially sweetened preserves and jams predate the nutrient content claim provisions of § 130.10. Removal of the artificially sweetened standards of identity would mean that products that are currently subject to the requirements of §§ 150.141 and 150.161 would instead be subject to the requirements of § 130.10, the general definition and standard of identity for foods named by a nutrient content claim defined in part 101. Thus, these products would be named by use of a nutrient content claim (e.g., “reduced calorie” or “no sugar added”) along with a standardized term (“jelly” or “jam”), in accordance with § 130.10. Revoking §§ 150.141 and 150.161 also would promote honesty and fair dealing in the interest of consumers by requiring manufacturers to more accurately and consistently describe the attributes of the food (e.g., less sugar or reduced calories); would allow any safe and suitable non-nutritive sweetener to be used in standardized

jams, jellies, and preserves; and would allow better comparison to other jams, jellies, and preserves currently modified under the provisions of § 130.10. For example, under current requirements, a jelly that is sweetened with saccharin must be called “artificially sweetened jelly” (in accordance with § 150.141) whereas a similar jelly sweetened with aspartame may be named as “reduced sugar jelly” (in accordance with § 130.10 and provided it meets the requirements for the nutrient content claim “reduced sugar” in § 101.60.(c)(5)) to distinguish it from the standardized food (jelly in § 150.140). Revoking the standards would provide consistency and uniformity among such products because all fruit spreads sweetened with non-nutritive sweeteners would be subject to the same requirements. This proposed rule also is consistent with FDA’s proposed general principles for modernizing food standards (70 FR 29214; May 20, 2005). In addition, this proposal is consistent with Executive Order 12866 of September 30, 1993 (58 FR 51735), and Executive Order 13653 of January 21, 2011 (76 FR 3821), regarding improving Agency regulations, regulatory planning, and regulatory review.

Considering the information in this document, we are proposing to revoke the standards of identity for artificially sweetened jelly, preserves, and jams in §§ 150.141 and 150.161, respectively. We request comments on our tentative conclusion that these two standards of identity are obsolete and unnecessary, and that revoking them would promote honesty and fair dealing in the interest of consumers.

#### IV. Analysis of Impacts

We have examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104-4).



Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. We tentatively conclude that this proposed rule is not a significant regulatory action as defined by the Executive Orders.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because we have tentatively concluded, as set forth in this document, that this rule would not generate significant compliance costs, we expect that this proposed rule, if finalized, would not have a significant economic impact on a substantial number of small entities. We request comment on the impact of this rule on small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is \$139 million, using the most current (2011) Implicit Price Deflator for the Gross Domestic Product. We do not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

### A. Need for This Regulation

We are proposing to revoke the standards of identity for artificially sweetened jelly, preserves, and jams because we have tentatively concluded that these standards are obsolete and unnecessary. The current standards of identity for artificially sweetened jelly (§ 150.141) and artificially sweetened preserves and jams (§ 150.161) provide that they may be manufactured only with specific, non-nutritive artificial sweeteners: saccharin, sodium saccharin, calcium saccharin, or any combination thereof. These standards of identity, therefore, do not permit the use of newer, safe and suitable artificial sweeteners, such as aspartame.

The development of newer artificial sweeteners and the enactment of the NLEA have made the current standards of identity for artificially sweetened jelly, preserves, and jams obsolete. The NLEA and § 130.10 permit the modification of a traditional standardized food to achieve a nutrition goal, such as a reduction in calories. Section 130.10(d)(1) allows the addition of safe and suitable ingredients to a food named by use of a nutrient content claim and a standardized term when these ingredients are used to, among other things, add sweetness to ensure that the modified food is not inferior in performance characteristic to the standardized food, even if such ingredients are not specifically provided for by the relevant food standard. Standardized jelly and standardized preserves and jams products modified under § 130.10 must use nutrient content claims to communicate the modified standardized product's nutritional profile to consumers. Under § 130.10, nonspecific, safe and suitable artificial sweeteners other than the three named in §§ 150.141 and 150.161 can be used to make reduced calorie or reduced sugar products labeled with a nutrient content claim that is established in FDA regulations. Revoking the standards of identity, as proposed, would mean that any product subject to §§ 150.141 and 150.161 would instead be subject to § 130.10. This would allow consumers to

better compare any fruit spreads currently covered by §§ 150.141 and 150.161 with other spreads that are named and modified under the provisions of § 130.10. Revoking the standards would also provide manufacturers with the flexibility to use the three non-nutritive sweeteners listed in §§ 150.141 and 150.161, while naming their products under the provisions of § 130.10 using a defined nutrient content claim.

### B. Regulatory Options

In assessing our regulatory options, we considered the option of taking no action and the option of taking the action proposed by this rule. We have tentatively concluded that the proposed rule, if finalized as proposed, would not be an economically significant regulatory action. We are not quantitatively estimating the benefits and costs of the regulatory alternatives to the proposed rule. In the following paragraphs, we qualitatively compare the costs and benefits of the regulatory options to the costs and benefits of the proposed rule.

#### 1. The Option of Taking No Action

By convention, we treat the option of taking no new regulatory action as the baseline for determining the costs and benefits of the other options. Therefore, we associate neither costs nor benefits with this option. The consequences of taking no action are reflected in the costs and benefits associated with taking the action set forth in this proposed rule.

#### 2. The Option of Taking the Proposed Action

If the proposed rule is finalized as proposed, and we revoke §§ 150.141 and 150.161, products that are currently subject to the requirements of these standards of identity would no longer be required to use the phrase “artificially sweetened” as part of their product name. Furthermore, revoking §§ 150.141 and 150.161 would mean that these same products would be

permitted to bear nutrient content claims along with a standardized term (e.g., “reduced calorie jelly” or “no sugar added jam”), in accordance with § 130.10.

The costs of this proposed rule, if finalized as proposed, would result from the need to relabel any existing jelly, preserves, and jams that conform with the standards in §§ 150.141 and 150.161. Any products currently manufactured in accordance with the standards in §§ 150.141 and 150.161 would have to be relabeled in order to comply with § 130.10 if this proposed rule is finalized as proposed. Our review of supermarket scanner data for the years 2001 through 2010, however, revealed that no such products are currently being sold. Sales for products manufactured in accordance with §§ 150.141 and 150.161 were last reported in 2002. A memorandum summarizing the results of this scanner data can be found in Reference 1. The data support our tentative conclusion that most manufacturers most likely have discontinued production of artificially sweetened jelly, preserves, and jams, presumably because of a perception that the phrase “artificially sweetened” is unattractive to consumers. The data also support our tentative conclusion that it is unlikely that this proposed rule would generate significant compliance costs due to the need to relabel products. In fact, removal of the artificially sweetened standards of identity would allow manufacturers to re-introduce products covered under §§ 150.141 and 150.161 to be sold as products covered by § 130.10. That is, they would be named by use of a nutrient content claim in conjunction with a standardized term (e.g., “reduced calorie jelly” or “no sugar added jam”), in accordance with § 130.10. Therefore, we tentatively conclude that any relabeling compliance costs would be negligible.

We do not classify as anticipated costs of this proposed rule, if finalized as proposed, any expenses that firms might voluntarily incur if they choose to change their product formulas or manufacturing practices in response to the proposed revocation of the “artificially sweetened”

standards of identity. Any such costs are not costs that would be required by this proposed regulatory change. Instead, these costs would result from voluntary business decisions made by manufacturers.

We tentatively conclude that the principal benefits that would result from the proposed rule, if finalized as proposed, derive from increased information and flexibility. Revoking the artificially sweetened standards of identity would provide producers of jelly, preserves, and jams with the flexibility to use saccharin, sodium saccharin, calcium saccharin, or any combination thereof, in their formulations without having to include the term “artificially sweetened” in their product names. Manufacturers could instead name their products in accordance with approved nutrient content claims, as provided for under § 130.10, thus providing consumers with additional information about the nutritional profile of affected products. Additionally, revoking §§ 150.141 and 150.161 would assist consumers in comparing products covered by the standards with other similar jelly, preserves, and jams manufactured in accordance with § 130.10.

Accordingly, while we do not quantify the costs and benefits of this proposed rule, we tentatively conclude that potential benefits will outweigh any potential costs associated with the rule.

### C. Initial Regulatory Flexibility Analysis

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because compliance costs, if any, generated by this proposed rule are expected to be negligible, we tentatively conclude that this proposed rule, if finalized, would not have a significant economic impact on a substantial number of small entities. We request comment on this tentative conclusion. The following

analysis, in conjunction with the discussion in this document, constitutes our initial regulatory flexibility analysis as required by the Regulatory Flexibility Act.

This proposed rule, if finalized, would revoke the standards of identity for artificially sweetened jelly, preserves, and jams. The revocation of these artificially sweetened standards of identity would provide small fruit spread firms with the flexibility to use the three non-nutritive sweeteners listed in §§ 150.141 and 150.161 and to name their products with FDA-defined nutrient content claims in accordance with § 130.10, as is currently done for fruit spread products manufactured with other non-nutritive sweeteners.

We do not classify as costs of this proposed rule any expenses that some small firms might voluntarily incur because they choose to change their product formulas or manufacturing practices in ways that would be permitted by the proposed rule, if finalized. As discussed in this document, any such costs would not be costs required by this proposal, if finalized. We request comments on the provisions of this proposed rule that might require small firms to change their current practices.

## V. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. Section 4(a) of the Executive order requires Agencies to “construe...a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.”

Section 403A of the FD&C Act (21 U.S.C. 343-1) is an express preemption provision. Section 403A(a) of the FD&C Act provides that “no State or political subdivision of a State may

directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce--(1) any requirement for a food which is the subject of a standard of identity established under section 401 that is not identical to such standard of identity or that is not identical to the requirement of section 403(g).”

The express preemption provision of section 403A(a) of the FD&C Act does not preempt any State or local requirement respecting a statement in the labeling of food that provides for a warning concerning the safety of the food or component of the food (section 6(c)(2) of the NLEA, Public Law 101-535, 104 Stat. 2353, 2364 (1990)).

This proposed rule, if finalized, would impose requirements that fall within the scope of section 403A(a) of the FD&C Act.

#### VI. Environmental Impact

We have determined under 21 CFR 25.32(a) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

#### VII. Paperwork Reduction Act

We conclude that the provisions of this proposed rule are not subject to review by the Office of Management and Budget because they do not constitute a “collection of information” under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520).

#### VIII. Comments

Interested persons may submit either written comments regarding this document to the Division of Dockets Management (see ADDRESSES) or electronic comments to <http://www.regulations.gov>. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received

comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

#### IX. Reference

The following source has been placed on display in the Division of Dockets Management (see ADDRESSES) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and is available electronically at <http://www.regulations.gov>.

1. Memorandum to the file, from Cristina McLaughlin, FDA, November 26, 2012.

#### List of Subjects in 21 CFR Part 150

Food grades and standards, Fruits.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, and redelegated to the Associate Commissioner for Policy and Planning, it is proposed that 21 CFR part 150 be amended as follows:

#### PART 150--FRUIT BUTTERS, JELLIES, PRESERVES, AND RELATED PRODUCTS

1. The authority citation for 21 CFR part 150 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 343, 348, 371, 379e.

§§ 150.141 and 150.161 [Removed]

2. Remove §§ 150.141 and 150.161.

Dated: November 27, 2012.

Leslie Kux,

Assistant Commissioner for Policy.



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